HML Ethics Review Board

Research Ethics Review Document

Review of UNICEF Research Project Materials for the Protection of Human Subjects

v.2023.2

This document serves to meet UNICEF ethical standards in research and is the official record of an ethics review. It is designed to ensure effective processes and accountability for ethical oversight and to ensure the protection of, and respect for, child and adult rights within all research, evaluation, and data collection processes undertaken or commissioned by UNICEF. It conforms with the UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis; Document Number: CF/PD/DRP/2015-001; Effective Date: 01 April 2015, Issued by Director, Division of Data, Research and Policy.

The Purpose of Research Ethics Review

The purpose of an Ethics Review Board (ERB) or Institutional Review Board (IRB) is the protection of human research subjects' rights. These rights include *Respect* for individuals to make free decisions, *Justice or equity* regarding distribution of the burdens and benefits of research, and *Beneficence* or the obligation to do good and avoid harm.

ERBs review research protocols that involve the collection and analysis of data from human subjects to ensure that ethical standards are upheld. This is to protect the rights and welfare of subjects and to ensure that:

- subjects know the purpose of the study and are not placed at undue risk;
- participation is voluntary and confidential;
- subjects are provided and agree to informed consent prior to their participation;
- relevant protocols are in place to assure subjects' protection and safety, and;
- data collection and analysis does not result in the violation of privacy or discrimination.

Before issuing approval, the ERB must determine that the following requirements are satisfied:

- informed consent is sought from each subject or the subject's legally authorized representative;
- the proposed research design is scientifically sound and that risks to subjects are minimized;
- any risks to subjects are reasonable in relation to anticipated benefits;
- subject selection is equitable;
- safeguards are included for subjects likely to be vulnerable to undue influence or coercion;
- subjects' safety, privacy, and confidentiality are maximized.

Materials Requested for Review:	**Also, please include:**
1. Inception Report / Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, subject recruitment, subject protection and data protection plans. 2. Copies of all Informed Consent documents. 3. Copies of all data collection instruments.	4. Written protocols to ensure subjects' safety.* 5. Written protocols for the protection of human subjects' identities.* 6. Written protocols for the protection of data.* 7. Other relevant documents. *These may be statements incorporated into research plans and/or embedded in a single protection protocol. .

HML IRB is an autonomous committee authorized by the United States Department of Health and Human Services, Office for Human Research Protections (IRB #1211, FWA #1102, IORG #850), to review and approve research involving human subjects before the start of research, and to conduct annual reviews of that research independent of affiliation with the research organization submitting materials for review.

Please submit your materials in English for review to:
D. Michael Anderson, PhD, MPH, HML IRB Chair & Human Subjects Protections Director
and Penelope A. Lantz, JD, HML IRB General Counsel
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UNICEF Research Ethics Review for Human Subjects' Protections

→ INVESTIGATORS: Please confirm your project information and any additional information requested below.

Section 1	**Project Overview** **Please provide any requested information**	
1.1	**Project Title:**	***Evaluation of Cash for Education (2021-2023)***
1.2	**HML IRB Research Ethics Review ID#:**	795LEBA23
1.3	**Initiating UNICEF Official:** Name, office, email	Emmanuel Saka, Evaluation Specialist, Regional Evaluation Section MENARO, esaka@unicef.org
1.4	**Principal Investigator/Project Manager:** Name, degree(s), organization, & address	Dr. Pamela Wridt, BSE, MAG, MA, PHD Evaluation Team Leader United States Please provide address 1091 Herkimer Street, Unit 2 Brooklyn, NY 11233
1.5	**Other Key Personnel:** Names & titles	Dr. Maha Mouchantaf, Education Expert, Lebanon
1.6	**Contracting Firm:** Name & address	Samuel Hall - Mindset
1.7	**Primary study site(s):** CO, RO, countries	Lebanon
1.8	**Project duration:** Dates from -- to	Sep 27, 2023 through Oct 31, 2023
1.9	**Duration of Subjects' Participation:** Dates from -- to	Please provide dates October 9 – 22, 2023
1.10	**Thematic Area/Areas:**	Education Choose an item. Choose an item.
1.11	**Target population:**	Parents of children ages 3 to 14.

Date of ERB Request	20 September 2023
Date(s) ERB Comments Returned	25 September 2023
Date Final Documents Received	28 September 2023
DATE OF ERB APPROVAL	28 September 2023

UNICEF Ethics Review Process

HML Ethics Review Board (UNICEF LTAS 42107154) will conduct a research ethics review of submitted materials and make comments below under **Additional Information Needed**. We will then return this template for responses from investigators.

Please respond to our comments in another colour, directly under each comment.

- Please provide any requested or revised materials, and please note where revisions to your materials may be found by page or paragraph number.
- Please do not alter ERB comments or the format of this document.

This HML ERB review document serves as the official record of the ethics review for the project named below. This document, including all comments and responses, will be retained by UNICEF and HML ERB as a confidential record of this review. Once you and we have agreed on the ethical rights of your research subjects, we will issue a letter of approval.

	Ethics Review Board Criteria of Interest	Additional Information Needed → Investigators: Please respond to ERB info requests in another color directly below the request	X or NA equal PASS (for ERB use)
Section 2	***ERB Submission:*** **Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:**		
2.1	**Inception Report or Research Protocol……..……X** e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans		X
2.2	**Informed Consent documents……..…X**		X
2.3	**Surveys and data collection instruments……..…X**		X
2.4	Written protocols to ensure subjects' safety		X
2.5	Written protocols for protection of subjects' identities		X
2.6	Written protocols for protection of data		X
2.7	Other relevant documents		X
2.8	Is *UNICEF Procedure for Ethical Standards* cited? Cited		X
2.9	Have informed consent and data collection instruments been pre-tested? a. yes……..……..X b. no……..…..…….. c. NR……..……..	Please respond. Yes, these forms have been used with similar participants on UN projects in Liberia, Jordan, Eritrea and other countries similar to Lebanon.	X
2.10	Are all submitted documents final versions? a. yes……..……..X b. no……..…..…….. c. NR……..……..	Please respond. The final consent forms were revised based upon guidance from this review. The final versions are attached to this message.	X
2.11	May the final protocol and instruments be included in an internal UNICEF searchable database for colleagues to learn from your work?	Please respond: INCLUDE or OMIT? Yes, please INCLUDE	X
2.12	Additional comments or suggestions		X

Section 3	***Research Design:*** **Do submitted materials describe the proposed research? This includes:**		
3.1	Is the study's background, rationale, and study design scientifically sound?		X
3.2	Type of data collection: a. survey questionnaire……..……..….. b. subject interview……..…….. c. key informant interview (KII)……..……...X d. focus group discussion (FGD)……..…..…..X e. secondary document (desk) review……X f. on-site observation…… g. case study…….. h. physical measurements …….. i. biological specimen ……..…… j. other..……..		X
3.3	Is the type of data collection appropriate for this study design?		X
3.4	Are secondary data (desk review including documents, reports, publications): a. publicly available....…… b. not publicly available containing personally identifiable information (PII)…… c. not publicly available containing no PII.....……X		X
3.5	Are types of data and variables in the secondary data set described?		X
3.6	Is how investigators' access to the secondary data described?		X
3.7	If the secondary data contained subject records, did subjects consent to reuse of their data?		X
3.8	Does study involve intervention, treatment, comparison, or control groups? a. intervention……..……...……X b. comparison…… c. control…….. d. none……	All parent subjects received the benefit, correct? Yes, any parent that volunteers to participate will receive the benefit of a snack and we also recently agreed to pay all invited parents $5 USD for transportation to the community center for the session.	X
3.9	Number of Data Collections:		X

	a. one-time only……..……..……X b. two or more (e.g., pre-post) ……		
3.10	Sample size: Approximate total *n* = 147	Correct? Yes, this is our estimated total sample for KIIs and sessions with parents. Parent sample = 120 KIIs = 27	**X**
3.11	Are any subjects children (<18 years old)?....None a. 0 – 2……..……..……..…… b. 3 – 7…… c. 8 – 12…….. d. 13 – 17……		**X**
3.12	Does study include the use of technologies (e.g., on-line data collection or intervention, *U-Report*)?		**X**
3.13	Additional comments or suggestions		**X**
Section 4	***Subject Risks:* Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?**		
4.1	Is the research *Minimal Risk* Only?: This means the probability and magnitude of anticipated harm or discomfort is no greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests.		**X**
4.2	Does the research involve *greater than minimal risk*, but where risks are justified by anticipated benefits; where the relation of the anticipated benefits to risks is at least as favorable as available alternative approaches; and where the intervention or procedure is likely to yield generalizable knowledge? If so, are mitigating procedures described?		**X**
4.3	Do study objectives show that risks are reasonable in relationship to expected gains and benefits are clearly articulated?		**X**

4.4	By their participation, are subjects vulnerable to any of the following?: a. physical risk ……. b. psychological risk ……..…..X c. social risk ……..…….….. d. economic risk ……..……..... e. legal risk …….……..... f. political risk ……..…….. g. employment risk…… h. academic risk……..... i. religious risk……..…... j. other……... k. none……...		X
4.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?		X
4.6	Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms, or access to services?		X
4.7	Do gender, ethnicity, or other demographic characteristics -- or grouping of subjects by any of these characteristics, especially in FGDs -- increase subject risk?	Are subjects only stratified by the age, gender, or disability status of their child? Yes the sample is stratified by these variables, but as mentioned in Annex C and in section 3.2.6, we will also include parents who have Lebanese and non-Lebanese children in our sampling strategy. Are there other variables (subject gender, etc.)? As mentioned in the Inception Report in section 3.2.6, we will strive to have a balance in parents by gender, an equal representation of both mothers and fathers.	X
4.8	If a subject discloses or is suspected to be at risk outside the study, are procedures in place to address or report risk and refer subject for relevant support?	Please describe. Yes, procedures are in place. Please refer to the updated Inception report, Ethical Protocol Section (page 10	X

4.9	Is local reporting abuse of children mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	Please respond. No children are included in this evaluation. Due to the nature of the evaluation, this is a minimal risk study and the evaluation does not in any way bring about any subject related to violence or abuse in minors or adults. It is highly unlikely that disclosure will be made by parents, however, in the case that it is done, or witnessed, research staff and data collectors are not mandated to report. They will be provided with referral mechanisms if requested and consented by the participant.	X
4.10	Additional comments or suggestions		X
Section 5	***High Risk:*** **When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?**		
5.1	Can subjects be perceived as vulnerable, including: children, especially unaccompanied or separated (UASC); lacking WASH, food, shelter, or medical care; refugees in conflict or post conflict; those in natural, ecological, or disaster settings; mothers & pregnant women; forced migrants and illegal or undocumented immigrants; prisoners or persons in institutions including orphanages or juvenile justice systems; gang members; those with mental or physical illness or disability; those with HIV/AIDS; those at economic or educational disadvantage; persecuted minority groups, or under high familial, peer, or social pressure? If yes, are study-specific protection protocols provided?		X
5.2	Does the sampling strategy target people at risk for issues such as: violence, torture, abuse, kidnapping; sexual exploitation, harassment, prostitution or pornography, female genital mutilation or cutting,		X

	reproductive or sexual issues; sexual orientation; child, early or forced marriage; suicide? If yes, are study-specific protection protocols provided?		
5.3	Are subjects involved in any of the following: slavery, including the sale and trafficking of children; forced labour, servitude, forced recruitment to armed groups; war or armed conflict; illegal activities, production or trafficking of drugs; economic exploitation; work that could damage health or safety; removal of organs for exploitation? If yes, are study-specific protection protocols provided?		X
5.4	Does the study request information relating to illegal activities? If yes, is an MOU in place with government to ensure that no participant is prosecuted? Have participants been notified of this agreement?		X
5.5	Additional comments or suggestions		X
Section 6	***Recruitment:*** **Do submitted materials describe subjects and the recruitment process?**		
6.1	To what extent are subjects identified: a. names are recorded with responses……. b. names recorded separate from responses…….. c. no names are recorded ..……..……X d. other PII is recorded……..…….. e. no PII is recorded ……X f. subjects are given a unique identifier..... g. other…….…..…		X
6.2	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?		X
6.3	Are subject recruitment procedures & sampling strategy adequately described?	If NGOs and other local partners conduct recruitment, will they know who participates or refuses? The NGOs will invite up to 20 parents to attend the session based upon a random sampling of parent beneficiaries, knowing that we may only have 12 in the end who show up the day of the session and who may be willing to consent to the process. Only the evaluators	X

		will know who agreed to participate in the end, as no NGO facilitators will be in the session.	
6.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?		X
6.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?		X
6.6	If subjects are children or other vulnerable groups, or if subject matter is sensitive, is recruitment sensitive to subjects' potential vulnerabilities (real or perceived) and does it ensure privacy throughout recruitment?		X
6.7	Do recruitment procedures show indication of bribery, coercion, intimidation, compulsion, pressure, or force?		X
6.8	Is recruitment of some members of the population and not others likely to result in resentment for either inclusion or exclusion? Have strategies to address this been adequately described?		X
6.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?		X
6.10	If subjects are paid, compensated, provided a gift, or provided other benefits or services for participation, is the incentive described and justified as non-coercive? a. cash or gift card…….. b. refreshment……..X c. travel cost……. d. phone or internet credit…….. e. small gift…… f. other…….. g. none…….. h. no response…….		X
6.11	Additional comments or suggestions		X

Section 7	***Informed Consent:*** **IC is a negotiation whereby subjects are informed about the study and their rights, and they agree to participate voluntarily. IC must be sought from each subject or the subject's authorized representative confirming this process.**		
7.1	Type of Informed Consent: a. written & signed ……..……. b. written not signed ……. c. written & signed by authorized representative.... d. written with online checkbox……..…… e. verbal & signed or recorded…….. f. verbal & signed by authorized representative…. g. verbal not signed or recorded……..…….X h. active…… i. passive…….. j. other ……		**X**
7.2	Are the processes for obtaining each IC adequately described?	Is there a reason you don't ask UNICEF subjects if they agree to participate? UNICEF staff members are required to participate in evaluation activities if requested. I added a line to the IC for UNICEF staff asking them if they want to participate, but in reality they are required. Please consider having a way to document or record consent. The consent will be documented by the evaluation team and will factor into the description of the final sample in the evaluation report.	**X**
7.3	Does the IC include a clear and simple invitation to participate, an explanation of what the subject will be expected to do, and why they are being recruited?		**X**
7.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?		**X**

7.5	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions or may withdraw anytime without consequences?	Please state on all ICs. All ICs already contain statements to this effect, for example: If at any time you feel you cannot answer a question, or prefer not to answer, please let me know and we will move onto other topics. If you prefer to not participate in the evaluation, that is okay too. Nothing bad will happen to you or your relationship with UNICEF.	X
7.6	Does IC include the expected duration of the subject's participation (hours/minutes)?	Please state on all ICs. All ICs already contain statements on the length of time required for each participant type. For example, the interview will last about one hour.	X
7.7	Are subjects given a clear indication of who will have access to their responses and in what form?		X
7.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?		X
7.9	Does IC include a description of any risks or benefits to subjects?	Please briefly include on all ICs. All ICs already contain statements on the benefits of participation (namely to improve UNICEF programmes) and risks of discomfort and their ability to stop participating at any time or to not answer any questions. For example, for parents: At certain times, you may feel upset or uncomfortable talking about your community or household conditions. You do not have to be in this activity if you do not want to be, or you can stop after we begin, that is okay too. You may say "No" to answering any questions. If you say "No" to answering any questions, nothing bad will happen to you or your family, and no one will be mad at you. No services will be withheld from you if you choose not to participate.	X
7.10	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?		X

7.11	Does IC provide identity and contact info of investigators? Is the form of contact useful and appropriate given power dynamics and access to resources like phones or email?	Please provide your contact information in all ICs. I added my contact details to the IC.	X
7.12	For child subjects, is IC being obtained from parent, guardian, caregiver, or authorized representative? If not, is a justification provided for why this is unnecessary?		X
7.13	For child subjects, is their role in the study described adequately and in an age and culturally appropriate manner for them to provide written or verbal *assent*?		X
7.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?		X
7.15	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?		X
7.16	Where data collection differs by method (e.g.: survey, FGD, interview, audio recording), do ICs cover each method?		X
7.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Please provide a copy to each subject. Noted. We will provide a copy to each subject in English or Arabic.	X
7.18	Additional comments or suggestions		X
Section 8	***Subject Protections:*** **Do submitted materials clearly identify protection against risk?**		
8.1	Do materials describe protocols for subjects' safety throughout data collection, analysis, storage, and dissemination?		X
8.2	Are all data collected necessary for the purposes of evidence generation?		X
8.3	Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security?		X
8.4	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?		X

8.5	Are backgrounds and qualifications of data collectors adequately described?		X
8.6	Have personnel collecting data from subjects, especially child subjects, had ethical training specific to the target group?		X
8.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
8.8	Additional comments or suggestions		X
Section 9	***Data Protections:*** **Do data collection and storage protocols adequately ensure subject & data safety?**		
9.1	Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity?		X
9.2	Do data collection procedures and environment ensure data security?		X
9.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?		X
9.4	If data will be shared with partners, is there a clear agreement or NDA?		X
9.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, management, and de-identification?	Please address transmission and management around the data. Especially in terms of security procedures that will be used. Please see Annex F, Data Management and Security Procedures for these details.	X
9.6	Do protocols state length of retention and destruction of raw data (months, years)? a. destroyed at end of study……..…….. b. destroyed after three years…… c. retained indefinitely…… d. other……..X 1 year after study completion e. NR	Please see Annex F, Data Management and Security Procedures for these details. After one year, the shared evaluation folder and all data will be deleted.	X
9.7	Additional comments or suggestions		X